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July 26, 2016

VIA FEDERAL EXPRESS AND U.S. MAIL

National Freedom of Information Officer
U.S. Environmental Protection Agency
1301 Constitution Avenue, NW
Room 6416 West
Washington, DC 20004
Phone: (202) 566-1667

National Freedom of Information Officer
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW (2822T)
Washington, DC 20460

Re: Request for Information Pursuant to the Freedom of Information Act

Dear Sir or Madam:

On behalf of our client, Dow AgroSciences LLC ("DAS"), we submit this request pursuant to the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, *et seq.* On April 19, 2016, EPA renewed its request for the raw data underlying an epidemiology study conducted by the Columbia Center for Children's Environmental Health at Columbia University, *The Mothers and Newborn Study of North Manhattan and South Bronx* (the "Columbia Study"). See Exhibit A. We understand that EPA has since received a letter in response to its April 19, 2016 request. We request that EPA provide us a copy of this letter.

This request does not apply to any documents or portions thereof that are Confidential Business Information. In addition, this FOIA request does not seek test data, manufacturing processes, or the confidential statement of formula for any pesticide product. Finally, this request does not seek any personnel, medical, or similar files subject to protection under FOIA Exemption 6, 5 U.S.C. § 552(b)(6) (2000).

We would be pleased to pay reasonable costs related to duplicating and shipping the requested information.

If we may be of assistance with this matter, please do not hesitate to contact me at (202) 857-6469. Thank you in advance for your assistance.

Sincerely,

A handwritten signature in blue ink that reads "Donald C. McLean". The signature is written in a cursive, flowing style.

Donald C. McLean, Esq.

Enclosure

Exhibit A



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 19 2016

Dr. Linda P. Fried
Dean, Mailman School of Public Health
Rosenfield Bldg., Mail Code: 722 West
168 14th St., 14th Floor
New York, NY 10032

Re: Columbia Center for Children's Environmental Health Epidemiology Study Data

Dear Dean Fried:

I am writing to continue the discussion our organizations have previously engaged in regarding the importance of the original data from the Columbia Center for Children's Environmental Health (CCCEH) epidemiology study in the EPA's assessment of chlorpyrifos risk to human health.

Information is the fundamental currency of environmental science, health science, natural resources, and related social science research, all of which are necessary to achieve EPA's mission of protecting human health and the environment. To help fulfill EPA's mission and support the regulatory and research goals of state and local governments and research institutions, EPA provides substantial financial support for scientific research through its grants programs. Every year, EPA awards over \$4 billion in funding for grants and other assistance agreements. In order for EPA to carry out its mission successfully, however, the public must also have confidence that EPA is appropriately using the scientific information it considers – including information developed through EPA grants programs. Transparency is ultimately the key to gaining the public's confidence in EPA's work. It is therefore critical that EPA's evaluation of scientific information be as transparent as possible. EPA and the National Institute of Environmental Health Sciences (NIEHS) jointly provided funding to the CCCEH between 1998 and 2003 for its investigation of links between pre- and postnatal exposures to environmental toxins and adverse impacts on fetal and early childhood growth and development. The work CCCEH has done in studying the long-term health effects of urban pollutants, including pesticides, on children raised in minority neighborhoods in inner-city communities since 1998 is vitally important in the understanding of organophosphate (OP) pesticide exposure's effect on neurobehavioral development. This is a fundamental issue that EPA has been investigating in its review of the insecticide chlorpyrifos, and the results from the CCCEH study is a key component of the EPA risk assessment.

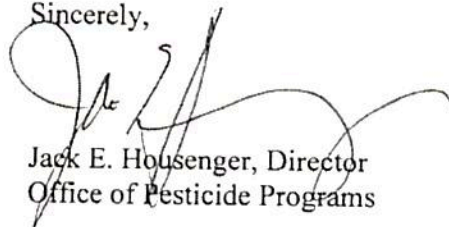
EPA has conducted systematic reviews of the scientific literature on epidemiology studies on neurodevelopmental outcomes associated with OP exposure in 2012, 2014, and 2015. Although other studies exist, the most robust epidemiology studies were conducted through three major U.S. based prospective birth cohort studies. The CCCEH study used concentration of pesticides (including chlorpyrifos) in umbilical cord blood as a measure of exposure, while the

other two birth cohorts used urinary biomarkers in the mothers to estimate pesticide exposure. While the studies using urinary biomarkers provide important supporting information, EPA believes the CCCEH study more accurately represents the dose that reaches the target tissue. It is for this reason that EPA considers the CCCEH research results most relevant for use in quantitative risk assessment.

On November 6, 2015, EPA proposed the revocation of all chlorpyrifos food residue tolerances, in part based on consideration of the CCCEH research. EPA is subject to a court-ordered deadline of December 30, 2016, to complete that action, and it is therefore imperative that EPA address all outstanding issues associated with this action by that time. EPA has recently concluded that the CCCEH research may in fact provide sufficient information to establish a new regulatory point of departure based on the neurodevelopmental outcomes observed in that research. To that end, EPA has developed an issue paper outlining its proposal for the use of the CCCEH study in quantitative risk assessment, and is soliciting feedback from the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) at a meeting from April 19 – 21, 2016. EPA will also be issuing a notice in connection with its proposal to revoke all chlorpyrifos tolerances that will, among other things, ask for additional public comment on EPA's increased utilization of the CCCEH research results.

Although EPA believes that the published results of the CCCEH research strongly support EPA's proposal to establish a new regulatory point of departure, it is important to note that the CCCEH researchers have, to date, not agreed to submit their underlying raw data to EPA to support our evaluation. While a team from EPA met with CCCEH staff in 2013 to discuss the conduct of the research and the raw data results, there is concern that in spite of our rigorous scientific analysis, the EPA has not been able to address our transparency goals as well as public feedback regarding access to the original ("raw") data. We were therefore pleased when we read the recent remarks of Columbia spokesperson Peter Taback in a Bloomberg BNA article noting that Columbia has offered to make its data available "under protocols that ensure the confidentiality of the children who are the subjects of our research. If we have a formal request from EPA, we will, of course, share all data that were gathered with the support of the U.S. government." While we are unaware of any previous offer from Columbia to submit these data to EPA, if in fact Columbia is offering to submit its research on chlorpyrifos to EPA so that it can be made available to the public (subject of course to any necessary restrictions to protect the confidentiality of the subjects in the study), we would welcome that development and will provide any assistance necessary to obtain these data. Accordingly, please consider this letter a formal request for this information. Please let me know if you have any questions or would like to further discuss. I can be reached at housenger.jack@epa.gov or at 703-308-8163.

Sincerely,



Jack E. Housenger, Director
Office of Pesticide Programs